



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

9/20/42

60 8th Street, N.E.
Atlanta, Georgia 30309

November 15, 2001

VIA FEDERAL EXPRESS

Benny Rippons, Owner
Benny's Seafood
5810 Old Ferry Dock Road
Manns Harbor, NC 27953

Warning Letter
02-ATL-08

Dear Mr. Rippons:

On August 16, 2001, an investigator from the Food and Drug Administration (FDA), Nancy E. Ford, conducted an inspection of your plant located at Manns Harbor, North Carolina. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh histamine-producing fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The HACCP deviations of concern are as follows:

1. Our review of your firm's HACCP plan for histamine-producing fish reveals that it is deficient and fails to meet requirements under 21 CFR 123.6(c) as follows:
 - a. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your HACCP plan does not list a critical limit for the adequacy of ice at the "Receiving" critical control point (CCP) even though it lists a monitoring procedure for the visual check of the adequacy of ice on incoming fish.

In addition, your critical limit at the "Storing Fish" CCP, i.e. "Keep fish temp. Below 50°" is not adequate to control the food safety hazard of histamine formation. As you may know, the histamine-forming bacteria can grow and produce histamine over a wide temperature range, even at moderate abuse temperatures such as 45°F. Ideally, the closer the product temperature is to the freezing point, the safer the product, and consequently, the longer its shelf life. It is common industry practice to prevent exposure of unfrozen histamine-forming fish to temperatures above 40°F for more than four hours, cumulatively, after chilling on board the harvest vessel.

We suggest that you refer to Chapter 7 of the *Fish & Fisheries Products Hazards & Controls Guidance, third edition* (copy enclosed), for guidance in establishing critical limits and monitoring procedures for controlling the histamine hazard in the fish you process.

- b. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan does not list the monitoring procedure and frequency at the "Storing fish" CCP to control the histamine formation hazard.
2. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures of checking the internal temperature of incoming histamine-producing fish, or performing a sensory examination for decomposition, for each lot of histamine producing fish received. Instead, your firm has been relying on an annual statement from the catcher that all fish are delivered within six hours from capture. We believe that this annual statement from the catcher does not provide adequate control of the histamine hazard.

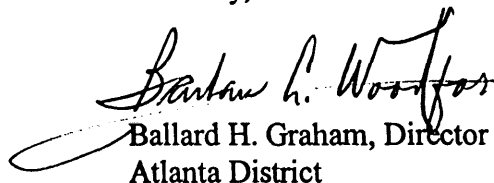
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,


Ballard H. Graham, Director
Atlanta District

Enclosure